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Reviews of Standards and Related Material*: Statistical Standards and ISO, Part 1

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ABSTRACT In this article we review the scope, structure, and directions of the International Organization for Standardization (ISO) Technical Committee TC69 on international statistical standards. Since its creation in 1948, ISO TC69 has published over 100 international statistical standards with several renewed periodically with revisions. The collection of 104 currently published standards is reviewed, and several standards at the final draft international standard (FDIS) stage are identified. Future strategic directions of TC69 are anticipated. The present article and subsequent articles are intended to complement the four-part series of papers on "Statistical Standards and ASTM" recently published in *Quality Engineering* (Fortini and Luko 2011; Murphy et al. 2011; Neubauer and Luko 2011; Ullman and Luko 2010).The goal is to inform the readership of the useful contents of the standards and to invite participation from experts through their standards' member bodies.

KEYWORDS International Standards Organization (ISO), statistical standards, Technical Committee 69 (TC69)

INTRODUCTION

It may come as a shock when a traveler ventures abroad and discovers that the electrical outlets differ from those at home. The utility line frequency (50 Hz or 60 Hz typically) can also vary from that used at home and can even vary within a country (e.g., western and eastern Japan. Note that this difference has inhibited the recovery from the tsunami in 2011). Lack of standardization with regards to left- and right-traffic sides is another example of undue duplicity and a circumstance in which correction to a single mode would likely be cost prohibitive (although Samoa switched from right to left in 2009 to match neighboring Australia and New Zealand). Standardization is perhaps best appreciated when it is absent. The International Organization for Standardization (abbreviated ISO from the Greek *isos* meaning equal) was founded in 1947 to deal with standardization issues across many sectors.

Standardization has been recognized since the time of the Chinese Zhou Dynasty (11th to 8th century B.C.) as a means for efficient and economical

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empire governance (Quipeng et al. 1995). At the heart of standardization is *metrology* (the science of measurement), which in turn necessitates statistical methods to cope with uncertainty in measurement as well as in characterizing a population on the basis of a sample of items. Issues related to ordnance in World War II (shortage of inspectors) prompted the development of acceptance sampling methods that could quickly identify very good or very bad lots based on relatively small samples and could prompt another round of sampling for intermediate quality lots. Boulanger et al. (1999) provided a concise history of standardization and couched international statistical standards in the context of the life cycle of products and services. They further delineated the following benefits of standardization:

- Enhanced product quality and reliability at a reasonable price
- Improved health and safety
- Improved environmental protection and reduction of waste
- Greater compatibility and interoperability of goods and services
- Reduction in the number of models, which in turn reduces costs
- Increased distribution efficiency
- Ease of maintenance

Statistical methods contribute to these areas, for example, through assessing measurement uncertainty and for calibrating, monitoring, and improving measurement processes in production (Perruchet 2008). Perruchet further noted that some agencies call for statistical methods in testing, verifying conformance, and validating the producer's quality and environmental management systems. The description above provides a rationale for the official scope of ISO TC69:

> Standardization in the application of statistical methods, including generation, collection (planning and design), analysis, presentation and interpretation of data. (http://www.iso.org)

The official scope actually applies broadly to statistical methods but covers the previously mentioned realms that are featured prominently in the overall portfolio of ISO standards.

STANDARDS CREATION AND PROGRESSION TO PUBLICATION

The production of standards proceeds through a well-defined process subject to detailed directives published jointly by the ISO and a sister standards organization—the International Electrotechnical Commission (IEC), which pioneered standardization in electrotechnology (electrical, electronic, and related technologies) in the early 20th century. In brief, a new international standard comes about first through the approval of a new work item with at least five member countries supplying experts to write the proposed document and a designated project leader under the aegis of a working group that has a designated convenor. This step of identifying project leaders and/or convenors can take place within the plenary meetings at international standards meetings typically held yearly. Recent meetings have occurred in Berlin (2011); Paris (2010, 2005); Kuala Lumpur, Malaysia (2009); Beijing (2008); Helsingør, Denmark (2007); Sun City, South Africa (2006); Stockholm (2004); Kansas City (2003); and Tokyo (2002).

With the approval of a new work item (via a ballot with a majority of the participating member countries), the proposed document goes through various stages starting from a working draft (WD), to a committee draft (CD), to a draft international standard (DIS), and, finally, to a final draft international standard (FDIS).Another class of documents that are guidelines rather than standards are technical reports (TRs), with prior stages being draft technical reports (DTRs). One other type of document is a technical specification (TS) document, which could be published, for example, if the technical committee was unable to reach sufficient support for the material as an international standard but nevertheless wanted the document to be published. At each stage, member countries can vote outright approval, approval with comments, disapproval with comments, or abstain. The process is extremely rigorous and the comments can be extensive, with each comment from each member body requiring a specific response prepared by the working group. Upon ultimate publication, the international standards are subject to periodic review, revision, and renewal. Throughout the process, ISO maintains a "clock" regarding the progression of the document through its various stages. Delays in meeting the schedule

TABLE 1 Sub-committee structure of ASQ TC69

Subcommittee or working group	Title	Secretariat	Chair(s) or convenor	Secretary
SC1	Terminology and symbols	ANSI (United States)	M. Johnson	A. Harris
SC4	Applications of statistical methods in process management	ANSI (United States)	J. Kim	J. Admussen
SC5	Acceptance sampling	BSI (UK)	D. Baillie	S. Cumberbatch
SC6	Measurement methods and results	JISC (Japan)	Y. Ojima	T. Sakaguchi
SC7	Applications of statistical and related techniques for the implementation of Six Sigma	Twin: SAC (China) and BSI (UK)	J. Sun and M. Boulanger (co-chairs)	S. Cumberbatch and Z. Yu
SC8	Application of statistical and related methodology for new technology	JISC (Japan)	H. Tsubaki	T. Sakaguchi
TC69/WG3	Statistical interpretation of data	AFNOR (France)	Jørgen Granfeldt, convenor (Denmark)	

can lead to the cancellation of projects, requiring later resuscitation as a new work item if the parties involved or new groups wish to continue. Note that the bulk of the work in writing the standards is done by volunteer experts whose other duties can intervene with the completion of projects.

OVERVIEW OF ISO TC69 STANDARDS

ISO TC69 is operated under the auspices of the French national organization for standardization, Association Française de Normalisation (AFNOR). Within ISO TC69, the production of standards is conducted by subcommittees (SCs) that handle multiple related standards and that are also under the auspices of various national organizations. Currently, ISO TC69 has the following subcommittees and working groups:

Each of the subcommittees or working groups is responsible for a number of documents with topic areas given by the title of each group. The published document areas will now be described with further details on the individual document reviews to appear in sequels to this article.

ISO TC69/SC1

Subcommittee 1 of TC69 is responsible for terminology and symbols. For many of the technical committees of ISO, the first numbered subcommittee deals with terminology. Clearly defined terms are essential to achieving harmony and consensus with the other standards produced by a technical committee. TC69 has three published standards on terminology with the series designation ISO 3534. The parts are as follows:

ISO 3534-1:2006: Statistics—Vocabulary and symbols—Part 1: General statistical terms and terms used in probability

ISO 3534-2:2006: Statistics—Vocabulary and symbols—Part 2: Applied statistics

ISO 3534-3:1999: Statistics—Vocabulary and symbols—Part 3: Design of experiments

Parts 1 and 2 were revised from earlier editions using concept diagrams, which are graphs showing the relationships among various terms. The terminology experts in ISO TC37 have led ISO in this direction to facilitate the development of terminology documents that have a coherent basis. Part 3 on design of experiments is within one favorable ballot of becoming an FDIS, which would then be published shortly thereafter as ISO 3534-3:2012. Working Group 2 within SC1 is also at the committee draft stage of ISO/CD 3534-4 on survey sampling. Resolutions were approved at the 2011 Berlin meeting to establish a new working group that will assist other SCs in developing terminology documents for statistical terms in the areas of Six Sigma and Lean Six Sigma, robust parameter design, and quality function deployment (QFD) that are not currently present in the ISO 3534 series.

ISO TC69/SC4

Subcommittee 4 of TC69 covers the area of statistical process control (SPC) including control charts, cumulative sum (CUSUM) charts, and process capability and performance. The current set of SC4 published documents is as follows:

ISO 22514-1:2009: Statistical methods in process management—Capability and performance—Part 1: General principles and concepts
ISO 22514-3:2008: Statistical methods in process management—Capability and performance—Part 3: Machine performance studies for measured data on discrete parts
ISO/TR 22514-4:2007: Statistical methods in process management—Capability and performance—Part 4: Process capability estimates and performance measures
ISO 21747:2006: Statistical methods—Process performance and capability statistics for measured quality characteristics
ISO 11462-1:2001: Guidelines for implementation of statistical process control (SPC)—Part 1: Elements of SPC
ISO 8258:1991: Shewhart control charts (with a correction in 1993)
ISO 7966:1993: Acceptance control charts
ISO 7873:1993: Control charts for arithmetic average with warning limits
ISO/TR 7871:1997: Cumulative sum charts—Guidance on quality control and data analysis using CUSUM techniques
ISO 7870-1:2007: Control charts—Part 1: General guidelines
ISO 7870-4:2011: Control charts—Cumulative sum charts

Document ISO 7871 is being withdrawn but the updated material will be incorporated in the ISO 7870 series of documents (eventually consisting of seven parts including Part 2: Shewhart control charts and Part 3: Acceptance control charts). The series ISO 22514 is also being expanded to additional parts. In addition to the published Parts 1, 3, and 4 listed above, there will be Part 2: Process capability and perfomance of time-dependent process models, Part 6: Process capability statistics for characteristics following a multivariate normal distribution, and Part 7: Capability of measurement processes. Ultimately, the complete set of these documents should prove very useful to practitioners.

ISO TC69/SC5

As briefly noted in the Introduction, acceptance sampling has been a staple among international statistical standards dueto its relevance to munitions and other areas of large-scale production requiring inspection procedures. The U.S. standard MIL-STD-105D on acceptance sampling was the forerunner to the ISO 2859 series of documents. Documents have been developed to standardize acceptance sampling methods involving sampling by attributes, by variables, and for cases where the items are in lots. Attention is also given to achieving various criteria with respect to the acceptance of parts or lots. Currently, the documents under the purview of SC5 are as follows:

ISO 2859-1:1999: Sampling procedures for inspection by attributes—Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (with corrections 2001 and 2011)
ISO 2859-2:1985: Sampling procedures for inspection by attributes—Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection
ISO 2859-3:2005: Sampling procedures for inspection by attributes—Part 3: Skip-lot sampling procedures
ISO 2859-4:2002: Sampling procedures for inspection by attributes—Part 4: Procedures for assessment of declared quality levels
ISO 2859-5:2005: Sampling procedures for inspection by attributes—Part 5: System of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ISO 2859-10:2006: Sampling procedures for inspection by attributes—Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes
ISO 3951-1:2005: Sampling procedures for inspection by variables—Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL (amended in 2009 and with revision underway as a CD)
ISO 3951-2:2006: Sampling procedures for inspection by variables—Part 2: General specification for

single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection of independent quality characteristics (with revision underway as a CD)

ISO 3951-3:2007: Sampling procedures for inspection by variables—Part 3: Double sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

ISO 3951-4:2007: Sampling procedures for inspection by variables—Part 4: Procedures for assessement of declared quality levels

ISO 3951-5:2006: Sampling procedures for inspection by variables—Part 5: Sequential sampling plans indexed by acceptance quality limit (AQL) for inspection by variables (known standard deviation)

ISO 8422:2006: Sequential sampling plans for inspection by attributes

ISO 8423:2008: Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)

ISO/TR 8550-1:2007: Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots—Part 1: Acceptance sampling

ISO/TR 8550-2:2007: Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots—Part 2: Sampling by attributes

ISO/TR 8550-3:2007: Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots—Part 3: Sampling by variables

ISO 13448-1:2005: Acceptance sampling procedures based on the allocation of priorities principle (APP)—Part 1: Guidelines for the APP approach

ISO 13448-2:2004: Acceptance sampling procedures based on the allocation of priorities principle (APP)—Part 2: Coordinated single sampling plans for acceptance sampling by attributes

ISO 14560:2004: Acceptance sampling procedures by attributes—Specified quality levels in nonconforming items per million

ISO 18414:2006: Acceptance sampling procedures by attributes—Accept-zero sampling system based on credit principle for controlling outgoing quality

ISO 21247:2005: Combined accept-zero sampling systems and process control procedures for product acceptance

ISO 24153:2009: Random sampling and randomization procedures

ISO 28801:2011: Double sampling plans by attributes with minimal sample sizes, indexed by producer's risk quality (PRQ) and consumer's risk quality (CRQ)

ISO TC69/SC6

Subcommittee 6 deals with metrology and measurement systems and is populated by both statisticians and physicists. One can discern from the list of SC6 documents given below that two of their major efforts went into the production of the ISO 5725 and ISO 11843 series of documents. Capability of detection is very important in determining the presence of toxic materials, for example, and issues related to accuracy (trueness and precision) are fundamental to all laboratory work.

ISO 5725-1:1994: Accuracy (trueness and precision) of measurement methods and results—Part 1: General principles and definitions (with correction 1998)

ISO 5725-2:1994: Accuracy (trueness and precision) of measurement methods and results—Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method (with correction 2002)

ISO 5725-3:1994: Accuracy (trueness and precision) of measurement methods and results—Part 3: Intermediate measures of the precision of a standard measurement method (with correction 2001)

ISO 5725-4:1994: Accuracy (trueness and precision) of measurement methods and results—Part 4: Basic methods for the determination of the trueness of a standard measurement method

ISO 5725-5:1998: Accuracy (trueness and precision) of measurement methods and results—Part 5: Alternative methods for the determination of the precision of a standard measurement method (with correction 2005)

ISO 5725-6:1994: Accuracy (trueness and precision) of measurement methods and results—Part 6: Use in practice of accuracy values (with correction 2006)

ISO 10576-1:2003: Statistical methods—Guidelines for the evaluation of conformity with specified requirements—Part 1: General principles

ISO 11095:1996: Linear calibration using reference materials

ISO 11843-1:1997: Capability of detection—Part 1: Terms and definitions (with correction 2003)
ISO 11843-2:2000: Capability of detection—Part 2: Methodology in the linear calibration case (with correction 2007)
ISO 11843-3:2003: Capability of detection—Part 3: Methodology for determination of the critical value for the response variable when no calibration data are used
ISO 11843-4:2003: Capability of detection—Part 4: Methodology for comparing the minimum detectable value with a given value
ISO 11843-5:2008: Capability of detection—Part 5: Methodology in the linear and non-linear calibration cases
ISO/DIS 11843-6: Capability of detection—Part 6: Methodology for the determination of the critical value and the minimum detectable value in Poisson distrbuted measurements by normal approximations
ISO/DIS 11843-7: Capability of detection—Part 7: Methodology based on stochastic properties of instrumental noise
ISO 13528:2005: Statistical methods for use in proficiency testing by interlaboratory comparisons (with revision underway with a CD)
ISO/DTR 13587: Three statistical approaches for the assessment and interpretation of measurement uncertainty
ISO/TS 21748:2010: Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation
ISO/TS 21749:2005: Measurement uncertainty for metrological applications—Repeated measurements and nested experiments
ISO/TR 22971:2005: Accuracy (trueness and precision) of measurement methods and results—Practical guidance for the use of ISO 5725-2:1994 in designing, implementing and statistically analysing interlaboratory repeatability and reproducibility results
ISO/TS 28037:2010: Determination and use of straight-line calibration functions

ISO TC69/SC7

Subcommittee 7 was established in 2008 in response to a perceived need to provide user-friendly documents of use to the Six Sigma community. In particular, the documents to be produced were planned to include detailed, interesting examples drawn from actual experiments and projects and would include output from statistical software packages (without suggesting a preference, which would violate ISO Directives). With these constraints in mind, SC7 elected to produce technical guideline documents that do not have the requirement for use as international standards but would illustrate sound practice and would draw upon existing international statistical standards as appropriate. Six technical guidelines or standards have been published with several others in intermediate stages of production. The six published technical guideline reports or standards are as follows:

ISO/TR 29901:2007: Selected illustrations of full factorial experiments with four factors (with correction 2009)
ISO/TR 12845:2010: Selected illustrations of fractional factorial screening experiments
ISO/TR 14468:2010: Selected illustrations of attribute agreement analysis
ISO/TR 12888:2011: Selected illustrations of gauge repeatability and reproducibility studies
ISO 13053-1:2011: Quantitative methods in process improvement—Six Sigma—Part 1: DMAIC methodology
ISO 13053-2:2011: Quantitative methods in process improvement—Six Sigma—Part 2: Tools and techniques

Documents likely to be published within the next few years cover the areas of response surface methods (ISO/TR 13195) and contingency table analysis (ISO/TR 16705).

ISO TC69/SC8

Subcommittee 8was the most recently established subcommittee (2009) in TC69 and was instigated by the need to produce statistical standards in support of quality management, without overlapping with the domain of ISO TC176 on quality managment and quality assurance. Working groups have been established to address robust parameter design and sampling associated with voice of the customer and preliminary design issues. Quality function

deployment and Design for Six Sigma (jointly with SC7) are also in the development stage.

ISO TC69/WG3

TC69 has produced other international standards that are not presently under the aegis of an existing subcommittee. Subcommittee 2 on applications of statistics and Subcommittee 3 on bulk sampling were disbanded and their work was assumed by TC69 because the member countries managing these SCs were no longer willing to make the financial commitment to continue. The published documents outside the existing SCs are as follows:

ISO 2602:1980: Statistical interpretation of test results—Estimation of the mean—Confidence interval
ISO 2854:1976: Statistical interpretation of data—Techniques of estimation and tests relating to means and variances
ISO 3301:1975: Statistical interpretation of data—Comparison of two means in the case of paired observations
ISO 3494:1976: Statistical interpretation of data—Power of tests relating to means and variances
ISO 5479:1997: Statistical interpretation of data—Tests for departure from the normal distribution
ISO 11453:1996: Statistical interpretation of data—Tests and confidence intervals relating to proportions (with correction 1999)
ISO 16269-4:2010: Statistical interpretation of data—Part 4: Detection and treatment of outliers
ISO 16269-6:2005: Statistical interpretation of data—Part 6: Determination of statistical tolerance intervals (revision underway as a CD)
ISO 16269-7:2001: Statistical interpretation of data—Part 7: Median—Estimation and confidence intervals
ISO 16269-8:2004: Statistical interpretation of data—Part 8: Determination of prediction intervals
ISO/TR 18532:2009: Guidance on the application of statistical methods to quality and to industrial standardization
ISO 28640:2010: Random variate generation methods

A major accomplishment of WG3 has involved the so-called monster document, ISO 18532, which is a tour de force in the use of statistical standards documents. This document supercedes the withdrawn document ISO/TR 13425, Guidelines for the selection of statistical methods in standardization and specification.

The residual documents on bulk sampling that remain in effect are as follows:

ISO 10725:2000: Acceptance sampling plans and procedures for the inspection of bulk materials
ISO 11648-1:2003: Statistical aspects of sampling from bulk materials—Part 1: General principles
ISO 11648-2:2001: Statistical aspects of sampling from bulk materials—Part 2: Sampling of particulate materials

SUMMARY

International statistical standards as provided in ISO published documents offer approaches to statistical concepts and issues that have achieved consensus through a laborious process requiring multiple layers of review by many countries. Areas of interest to the general statistical, Six Sigma, and quality management communities include traditional terminology, statistical process control, acceptance sampling, and metrology and measurement systems. Recognizing the customer demand for standards related to quality improvement, TC69 under the leadership of Dr. Christophe Perruchet created Subcommittees 7 and 8 to address the needs of the Six Sigma, Lean Six Sigma, and quality management communities. Tragically, Dr. Perruchet died ina motorcycle accident on June 3, 2011, but with the sustained efforts of the statistical standards experts, the momentum from these initiatives should continue and, in turn, further the legacy of Christophe's vision of TC69.

Subsequent articles in this series will delve into the published standards in more detail. Production of future standards documents depends on the population of experts willing to devote their time to this worthwhile effort. In the United States, experts are purely voluntary and are responsible for their own travel expenses.In other countries, some experts are paid by the standards bodies for work performed, and in other countries, experts actually must pay annually for the right to comment on pending documents! Statistical experts interested in participating

in this mentally rewarding activity should contact their country's standards body (e.g., in the United States, interested experts should contact standards@asq.org).

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